

REMARKS/ARGUMENTS

This Response is being submitted in response to the Office Action dated August 17, 2007. Claims 11-15, 19-26, and 28-32 are and remain pending in this application and claims 11-15, 19-26, and 28-32 stand rejected. Claims 1-10 and claims 16-18 and 27 were previously canceled. Reconsideration and reexamination are respectfully requested.

Rejections Under 35 U.S.C. § 112, first paragraph

Claims 11, 12, 13, 15, 19, 20, 21, 23, 24, 25, 30, and 31 stand rejected under 35 USC §112, first paragraph, in that the specification purportedly does not enable any person skilled in the art to make and practice the invention, and as purportedly failing to comply with the written description requirement. Specifically, the Examiner has stated that claims 11, 12, 13, 15, 19, 20, 21, 23, 24, 25, 30, and 31 stand rejected because the specification allegedly does not enable one skilled in the art to which the claims pertain to make and practice the invention commensurate in scope with these claims. Furthermore, the Examiner stated that claims 11, 12, 13, 15, 19, 20, 21, 23, 24, 25, 30, and 31 stand rejected because the claims contain subject matter not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention commensurate in scope with the claimed inventions; and furthermore, that "(t)he expression "root extract" does not define the ingredients. Applicants respectfully traverse this rejection for at least the reasons discussed below.

The application adequately enables one skilled in the art to make and practice the invention. The extraction process is described in the "DESCRIPTION OF THE PREFERRED EMBODIMENT" section of the initial patent filing. Specifically, the description sets forth, page 3, lines 18-28, the steps of:

"placing the [Kaempferia Galanga] root in an alcohol path, heating in the alcohol bath to extract the cinnamate from the root; separating the alcohol solution from the root residue, and thereafter heating the alcohol extract for a time sufficient to evaporate substantially all of the alcohol therefrom." pg. 3, ll.19-22.

The resulting “compound,” i.e., root extract (as it is referred to throughout the specification) “is then used to prepare topical cosmetic preparations.” pg. 3, ll. 23-24. One skilled in the art can follow these very specific steps to obtain the end product of the extraction process.

The result of the extraction process is a definite product, which thus is clearly enabled by the very specific process set forth in the specification. Applicants have thus satisfied the enablement requirement of the first paragraph of section 112. Applicant's use of the term "root extract" throughout the application is sufficiently definite, based on the definition of "root extract" clearly set forth in the application, particularly as defined by the above-cited process for extraction which results in the definite root extract product. Practitioners possessing the present specification can “make and use” the root extract product hereof. This is all that is required for statutory “enablement.

In the instant rejection, the Examiner urges that “[t]he expression **“root extract”** does not define the ingredient(s).” Office Action (OA), pg. 2, lines 13-14 (underlineation and bolding emphasis in the original). For enablement, this is not relevant, necessary, nor required. Practitioners need merely be taught how to “make and use” the invention. They have here, and thus the rejection is overcome, obviated or traversed.

Moreover, since a very specific and definite product is taught as being obtained by this very specific and definite disclosed process (see above, specification, page 3, lines 18-28), Applicants have also satisfied the written description requirement of section 112. Applicants did have possession of the claimed invention, as they had very definitely defined their root extract by the at least one definite extraction process set forth in the specification and above. Persons of skill in the art are also put on notice as to Applicants' possession of a definite product by the definition of the extract by the recitation of this extraction process. This is all that is necessary for the written description requirement of section 112.

In the instant rejection, the Examiner further urges that the “specification lack[s] support for the claimed **“root extract.”** OA, page 2, lines 15-16 (underlineation and bolding emphasis in the original). Applicants have controverted this by showing that the specification indeed teaches how to obtain the “root extract” hereof. Similarly, as to the prior statement that “[t]he expression **“root extract”**

does not define the ingredient(s)." Office Action (OA), pg. 2, lines 13-14 (underlineation and bolding emphasis in the original); here also, this is neither relevant, necessary nor required to satisfy the statutory "written description." Applicants were in possession of a root extract and the method for achieving same and further recounted all this in the specification. Written description is also satisfied.

Furthermore, it is irrelevant, unnecessary and not required of Applicants to address the issues urged by the Examiner as to the "great number of compounds that exist[] in the extraction of this plant material" (OA, pg. 3, ll 23-24); or the long listing in the OA, page 4, lines 3-15. These are simply not in issue for statutory enablement or written description.

Again, in this case, the structure of the initial application disclosure provides instructions for one skilled in the art to obtain a sufficiently definite "root extract" of Kaempferia Galanga. Despite examiner's listing of other elements that may be found in Kaempferia Galanga, such other ingredients are peripheral to this case. As the specification sets forth, which any other compounds may be present in Kaempferia Galanga may be found in the root extract; however, they scope and content of the root extract is defined by the extraction process and thus enabled and sufficiently described in the specification.

As a side note, the Office Action contains a note at the bottom of page 5, last two lines that the "Applicant has argued limitations on page 5 (presumably of their prior argument submittal, see Response of May 2, 2007) which limitations are not present in the instant claims pertaining to a product by process." First, as to enablement and written description, the claims are not directly the issue; rather, the specification is the issue, and, Applicants' present and prior response were so directed. Second, Applicants reference to the process for obtaining/defining the "root extract" of their case does not suggest nor require that the claims be product by process. That is another issue not properly addressed here; neither in rejection nor rebuttal.

As to the vague and indefinite rejection (presumably under 112, second paragraph), OA, page 6, starting line 2, or line 5, the examiner imposes the requirement that the applicant indicate in the claims the structure of the ingredients(s) or the compound(s) and the number of compound(s) effective for the claimed composition or a sufficient number of physical data to define the

compound(s) or to submit a product-by-process for claimed "root extract". Applicant has complied with the statutory requirement. The structure of the root extract of the claims is given in the specification as set forth above, see page 3, lines 18-28 of the specification, and is thus neither indefinite nor vague. Physical data for effectiveness of this structure are also represented (see Examples 4 and 5, pages 7-10). The structure is definite and the data are presented. The number of compounds effective for the claimed composition is of no matter; an extract as described hereby is effective regardless how many constituent elements may contribute.

Converse to the examiner's assertion that the term "root extract" does not define the ingredients, or "does not define structures, physical or chemical properties of compounds," OA, page 6, lines 22-23, the extraction process defines the expression "root extract". The term is clear and it defines the "metes and bounds" of the claimed invention. Note, Applicant has previously stated that use of the term "extract" is common in patent lexicography relating to derivatives of organic matter, as evidenced by the patents and prior art listed in the brief summary of the invention section of the initial patent filing. See also **Exhibit A**, US Patent Office database of patents issued since 1976 with claims including the phrase "root extract"; resulting in at least 77 patents since 1976 (<http://patft.uspto.gov/> ...); which doesn't even begin to reach all "extract" claims from seed extracts, plant extracts, or extracts from other living or non-living matter. Use of the term "extract" does not render the claims of a patent indefinite nor vague, as often the term "extract" may be the most accurate and complete means of describing a constituent and essential ingredient of the claimed invention. This may be true here, where it may be incomplete to refer to the identity of the effective ingredients without making reference to the means of derivation from a root or other organic material.

Applicants submit that the terms "extract" and "root extract" and its further definition in the disclosure and in the claims are definite for at least the above reasons. Accordingly, Applicants respectfully request that the Examiner reconsider and withdraw the rejection (presumably under 112, second paragraph) of claims 11, 12, 13, 15, 19, 20, 21, 23, 24, 25, 30, and 31, and respectfully request that the claims be allowed.

Rejections Under 35 U.S.C. § 102(b)

Claims 11, 12, 14, 15, 19, 20, 21, 22, 24, 25, 26, 28, 30, 31 and 32 stand rejected under 35 USC § 102(b) as purportedly being anticipated by Voss et al. (U.S. Patent No. 5,972,315; hereinafter "Voss"). Specifically, the Examiner has rejected these claims, "...in view of Example 1b, wherein the concentration of the ethyl p-methoxycinnamate is 2%." Claims 11, 12, 14, 15, 19, 20, 21, 22, 23, 24, 25, 26, 28, 30, 31 and 32 stand rejected under 35 USC § 102(b) as purportedly being anticipated by JP40815734 (hereinafter "Matsuda") in view of paragraphs 26, 29, 31, 41-43 and 49 of that patent, which allegedly contain extracts of the claimed plant material within the scope of the claimed percentages. Finally, claims 11-13, 15, 19-21, 23, 25 and 31 stand rejected under 35 USC § 102(b) as purportedly being anticipated by Schade, DE 19849514 (hereinafter "Schade"), which allegedly teaches isoamyl p-methoxycinnamate which is within the scope of the claimed inventions. Applicants respectfully traverse this rejection for at least the reasons discussed below.

Applicants' claim 11 recites:

A composition for protecting mammalian skin from discoloration or harmful effects of tyrosinase or chemically induced irritation other than UV radiation consisting essentially of an effective amount of up to about 5% by weight of a root extract of Kaempferia Galanga.

Applicants' claim 21 recites:

A composition for protecting mammalian skin from discoloration or harmful effects of tyrosinase or chemically induced irritation other than UV radiation comprising a preparation containing, in weight percent, an effective amount up to about 5 percent of a root extract of Kaempferia Galanga dispersed in a carrier.

Applicants' claim 26 recites:

A composition for protecting mammalian skin from discoloration or the harmful effects of tyrosinase or chemically induced irritation other than UV radiation comprising a preparation containing, in weight percent, an effective amount up to about 5 percent of ethyl p-methoxycinnamate dispersed in a carrier; wherein the ethyl p-methoxycinnamate is extracted from Kaempferia Galanga root.

Applicants' specification and claims disclose and teach a skin-care product, or the components thereof, for protecting against the harmful effects of tyrosinase or chemically induced irritation other than UV radiation, as taught by Applicants' specification and claimed in independent claims 11, 21 and 26. Conversely, Voss describes its skin-care product throughout as "a new cosmetic skin-care product against ageing of the skin as an effect of light", as in col. 1, line 1; col. 1, line 55; and col. 2, line 27. By limiting the Voss cosmetic skin-care product to this one function, Voss specifically does not include, teach or suggest the element claimed and taught by Applicant, which is protection against the harmful effects of tyrosinase or chemically induced irritation other than UV radiation.

Furthermore, the only mention of ethyl p-methoxycinnamate in Voss is in col. 4, line 47. The inclusion of ethyl p-methoxycinnamate, to the extent it is mentioned in this one instance, is as a UV B filter in the amount of 2.0 g in a total emulsion of 100 g. Voss limits inclusion of ethyl p-methoxycinnamate to this one Example 1b, and furthermore, limits the role of ethyl p-methoxycinnamate to the role of a UV B filter at a 2.0% concentration. By such limitation, Voss does not include, teach or suggest the "other than UV limitation" of Applicants' claims and rather, teaches away from use of ethyl p-methoxycinnamate as anything but a UV B filter in a 2.0% concentration. Applicants' composition's use of Kaempferia Galanga root extract serves an entirely different function than the Voss composition. Applicants' claimed composition is of a Kaempferia Galanga root extract as protective against the harmful effects of tyrosinase or chemically induced irritation but specifically does not include Kaempferia Galanga root extract as a protectant against UV radiation.

The examiner appears to state that the products are identical or substantially identical, and to require that the applicant prove that the prior art products do not inherently possess the characteristics of the claimed product. In re Brown, 459 F.2d 531 (CCPA 1972). As a preliminary matter, the products are different. The claimed product here is specifically intended for "protecting mammalian skin from discoloration or the harmful effects of tyrosinase or chemically induced irritation other than UV radiation". This is not an inherent characteristic of the Voss product, which "is based on UV-radiation-absorbing substances [necessarily] in combination with a free-radical scavenger system". Note, persons using the Voss product for treatment

of sunburn would not inherently be treating a tyrosinase or chemical irritant or discoloration issue as provided here. There is thus no inherency from Voss.

Similarly, the Matsuda patent is entitled "UV Absorptive Skin Cosmetic", and is described as "a UV absorptive skin cosmetic characterized by having high safety and comprising a plant extract having UV absorptive effect". The objective of the invention in Matsuda is to protect the skin against harmful UV light, unlike the objective of applicant's patent. Matsuda is a UV protectant. Applicants' invention is a non-UV protectant. These are not identical and thus Matsuda does not anticipate. Note here also, persons using the Matsuda product for treatment of sunburn would not inherently be treating a tyrosinase or chemical irritant or discoloration issue as provided here. There is thus no inherency from Matsuda.

The Schade patent, to the best of applicant's understanding, references neither extract of Kaempferia Galanga nor a non-UV protectant. The reference cited by the examiner is isoamyl p-methoxycinnamate, also known as amiloxate. The mere fact that the Schade reference teaches a UV protectant for a potential substituent of Kaempferia Galanga root extract does not teach or suggest the root extract itself nor as an "other than UV" protectant. Therefore, the Schade patent does not constitute disqualifying prior art.

In order to sustain a rejection under 35 USC 102(b), the cited reference (i.e. Voss, Matsuda, and Schade) must teach or disclose each and every element of the claimed invention. None of the cited references teaches each and every element of Applicants' amended claims 11, 21 and 26. Applicants' claims 11, 21 and 26 are believed to be allowable over Voss, Matsuda and Schade. Applicants' dependent claims 12-15, 19, 20, 22-25 and 28-30 are believed to be allowable over Voss, Matsuda and Schade because they depend from allowable independent claims 11, 21 and 26.

Rejections Under 35 U.S.C. § 103(a)

Claims 13, 23, 28 and 29 stand rejected under 35 USC 103(a) as purportedly being obvious over Voss et al. (U.S. Patent No. 5,972,315; hereinafter "Voss"). Specifically, the Examiner has rejected these claims, "...in view of Example 1b, wherein the concentration of the ethyl p-methoxycinnamate is 2% further in view of

the disclosure which teaches that the percentage range is as low as 0.1%..." Claims 11-15, 19-26 and 28-32 stand rejected under 35 USC 103(a) as purportedly being obvious over Matsuda. Specifically, the Examiner has rejected these claims, "...in view of the broad disclosure as noted by the abstract as well as the examples noted . . . which extracts contain at least the ethyl p-methoxycinnamate in the extract." Applicants respectfully traverse this rejection for at least the reasons discussed below.

Applicants incorporate their above arguments with regard to Voss, *supra*, and Matsuda, *supra*, and submit that Applicants' amended claims 13, 23, 28 and 29 are believed to be allowable at least, because: i) they contain limitations not taught or suggested by Voss or Matsuda; and ii) they depend from allowable independent claims 11, 21 and 26, respectively.

CONCLUSION

Applicants respectfully request that all rejections be obviated or traversed hereby and withdrawn. A timely Notice of Allowance is requested to be issued in this case. Applicants believe no fees or petitions are due with this filing. However, should any such fees or petitions be required, please consider this a request therefore and authorization to charge Deposit Account No. 02-2093 as necessary.

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Respectfully submitted,

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EXHIBIT A

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aclm/("root extract")

PAT.
NO.

Title

- 1 [7,282,224](#) **T** Pain relief composition
- 2 [7,276,258](#) **T** Herbal extract and compound lupinoside and its analogues as anti-diabetic type II drugs from plant Pueraria tuberosa
- 3 [7,250,180](#) **T** Anti-prostate cancer composition and therapeutic uses therefor
- 4 [7,214,507](#) **T** Plant enzymes for bioconversion
- 5 [7,201,930](#) **T** Licorice root extract oral patch for treating canker sores
- 6 [7,175,987](#) **T** Compositions and methods for treatment of herpes
- 7 [7,138,146](#) **T** Acrochordon alleviation
- 8 [7,115,285](#) **T** Composition and method for appetite and craving suppression and mood enhancement
- 9 [7,037,533](#) **T** Functional agent for decomposing nicotine and method of preparing the same
- 10 [7,037,522](#) **T** Nocturnal muscle enhancing composition and method
- 11 [7,025,955](#) **T** Method for maximizing scalp health and inducing enhanced visual and tactile hair quality
- 12 [6,989,165](#) **T** Synergistic composition for treating hyperlipidemia
- 13 [6,989,163](#) **T** Arrangement to enhance a woman's sexual sensitivity by a combination of phytoestrogens, L-arginine and menthol
- 14 [6,989,150](#) **T** Cosmetic preparation of active substances with a synergistically increased radical protection factor
- 15 [6,953,593](#) **T** Sustained-release microencapsulated delivery system
- 16 [6,888,043](#) **T** Feminine care products for the delivery of therapeutic substances
- 17 [6,841,176](#) **T** Immunity enhancing supplements for lung support

- 18 [6,800,292](#) T Pomegranate fruit extract compositions for treating dermatological disorders
- 19 [6,780,596](#) T Methods for determining the activity of complex mixtures
- 20 [6,746,697](#) T Composition containing Heliopsis longipes root extract and oral carrier
- 21 [6,719,966](#) T Creamy, stable homogeneous antiperspirant/deodorant composition
- 22 [6,710,076](#) T Hydroxy-kojic acid skin peel
- 23 [6,676,974](#) T Bioactive hexane fraction from *Vetiveria zizanioides*
- 24 [6,652,891](#) T Co-enzyme Q10 dietary supplement
- 25 [6,630,130](#) T Sunless tanning cream
- 26 [6,607,755](#) T Anti-aromatase pharmaceutical composition for controlling testosterone/estrone ratios
- 27 [6,605,296](#) T Natural substances based agent
- 28 [6,596,266](#) T Compositions containing minoxidil and saw palmetto for treating baldness
- 29 [6,586,018](#) T Herbal composition
- 30 [6,583,184](#) T Compositions having comfrey and methods for reducing retinoid-induced skin irritation
- 31 [6,541,045](#) T Herbal composition and method for combating inflammation
- 32 [6,541,042](#) T Therapeutically effective combination
- 33 [6,537,592](#) T Extracts of kava-kava
- 34 [6,524,626](#) T Ginseng berry topical products
- 35 [6,524,624](#) T Two-part disinfecting systems and compositions and methods related thereto
- 36 [6,521,268](#) T Antibacterial and anti-inflammatory compositions with *Inula helenium* L. extract and water soluble chitosan
- 37 [6,447,814](#) T Chinese herbal composition for improving blood circulation and the method of preparing the same
- 38 [6,440,402](#) T Photostable sunscreen compositions and methods of stabilizing
- 39 [6,426,080](#) T Cosmetic preparation of active substances with high protection factor against free radicals
- 40 [6,395,311](#) T Multicomponent biological vehicle
- 41 [6,352,685](#) T External preparation for skin
- 42 [6,348,503](#) T Method and topical treatment composition for herpesvirus hominis
- 43 [6,333,304](#) T Therapeutic compositions containing glucosamine, collagen and a bioflavanol for repair and maintenance of connective tissue
- 44 [6,322,838](#) T Mint and/or fruit flavor compositions
- 45 [6,319,523](#) T Composition and method for inhibiting oral bacteria
- 46 [6,312,736](#) T Herbal composition to relieve pain
- 47 [6,300,369](#) T Hydroxy-kojic acid skin peel
- 48 [6,261,607](#) T Composition for promoting prostate health containing selenium and herbal extracts
- 49 [6,242,012](#) T Herbal composition for promoting hormonal balance in women and methods of using same
- 50 [6,241,987](#) T Dietary supplement containing saw palmetto, pumpkin seed, and nettle root

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aclm/("root extract")

PAT.
NO. Title

- 51 6,221,372 T Cosmetic cleansing and skin care preparation containing plant and algae extracts
- 52 6,197,343 T Skin color improver
- 53 6,187,313 T Composition and method for treating and preventing helicobacter-pylori-associated stomach gastritis, ulcers and cancer
- 54 6,156,355 T Breed-specific canine food formulations
- 55 6,080,410 T Method for reducing daily stress and anxiety in adults
- 56 6,071,962 T Oxa acids and related compounds for treating skin conditions
- 57 6,025,363 T Composition for suppressing appetite
- 58 5,977,120 T Composition for achieving an alert, yet calm state
- 59 5,958,334 T Combination capable of forming an odor barrier and methods of use
- 60 5,942,232 T Composition with plant additives and treatment method for reducing stress levels in fish
- 61 5,916,564 T Tripterygium wilfordii Hook F extracts and components thereof for immunosuppression
- 62 5,900,251 T Internal breath freshener and digestive aid
- 63 5,874,463 T Hydroxy-kojic acid skin peel
- 64 5,869,540 T Herbal treatments for improving skin appearance
- 65 5,773,014 T Compositions and methods for inhibiting the formation of unwanted skin pigmentation
- 66 5,770,207 T Dietary supplements containing kava root extract, passion flower, chamomile flowers, hops, and schizandra fruit
- 67 5,660,833 T Anti-tussive composition

- 68 5,607,673 T Purified extract of uvaria brevistipitata and a process for obtaining the purified extract therefor
- 69 5,603,949 T Use of a tocopherol phosphate or one of its derivatives, for the preparation of cosmetic or pharmaceutical compositions and compositions so obtained
- 70 5,569,459 T Pharmaceutical compositions for the management of premenstrual syndrome and alleviation of menopausal disorders
- 71 5,510,113 T Composition based on hydrated lipidic lamellar phases or on liposomes containing at least one derivative of labdane, or a plant extract containing it; cosmetic or pharmaceutical, particularly dermatological composition containing it
- 72 5,455,033 T Medicinal composition for treatment of inflammation
- 73 5,424,331 T Pharmaceutical compositions and dietary soybean food products for the prevention of osteoporosis
- 74 5,294,443 T Tripterygium wilford II hook f extracts and components thereof for immunosuppression
- 75 5,198,217 T Topical demulcent for viral and inflammatory diseases of the skin
- 76 5,153,019 T Rice bran-honey based beverage product and process for making same
- 77 4,755,504 T Pharmaceutical composition from Tienchi

